

JUL - 5 2006

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

Office of Regulatory Policy HFD - 13 5600 Fishers Lane, Rockville, MD 20857

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,843,901. The application was filed on January 9, 2004, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Kery A. Fries

Senior Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner

for Patent Examination Policy

cc:

Jane Remillard

LAHIVE AND COCKFIELD, LLP

28 State Street Boston MA 02109

RE: Plenaxis® (abarelix) FDA Docket No. 04E-0425